REMARKS

The amendment to claim 2 does not add new matter. In particular, claim 2 has been amended to clarify the language and recite that "said graft is obtained from a porcine, bovine, equine, goat ~~and~~ or other ruminant ~~sources~~ source." For these reasons, the amendment to claim 2 is fully supported by claim 2 as originally filed and does not add new matter.

Summary of the Bases for Rejection

Claims 1, 2, 4, 8, 9, and 31-40 3, 7-11 are rejected under 35 U.S.C. §103(a) for being allegedly unpatentable over U.S. Pat. 5,067,962 ("Campbell") in view U.S. Patent No. 5,961,520 ("Beck").

I. 35 U.S.C. §103(a) Campbell in view of Beck

Claims 1, 2, 4, 8, 9, and 31-40 3, 7-11 are rejected under 35 U.S.C. §103(a) for being allegedly unpatentable over U.S. Pat 5,067,962 ("Campbell") in view U.S. Patent No. 5,961,520 ("Beck"). According to the Patent Office, Campbell discloses a "xenograft replacement ligament comprising a bone-ligament-bone attachment with a naturally occurring [ligament to bone] attachment (see abstract and Fig. 3)" and that "Figure 3 discloses bone blocks shaped into a dowel." [Official Action at page 2.] The Patent Office admits, "Campbell et al does not disclose a groove along the length of each bone block." [Official Action at page 2.]

To make up for the admitted deficiency in Campbell, the Patent Office cites to Beck. According to the Patent Office, Beck "discloses an artificial ligament comprising an anchoring system made of bone (see col. 6, lines 36-39) and having a groove along the length (see Fig. 2, see element 17) for the purpose of inserting an attachment screw and attach the attachment system to the patient's bone." [Official Action at page 2.] The Patent Office then concludes that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bone blocks of the Campbell et al. reference with **the longitudinal groove (see surface 17) of the Beck, Jr. et al. reference**, in order to insert an attachment screw and attach the attachment system to the patient's

bone." [Official Action at pages 2-3 (bridging sentence).] The Applicants respectfully disagree.

A. Campbell and Beck take divergent approaches that teach away from one another

"A prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or **would be led in a direction divergent from the path taken by the applicant.**" *Monarch Knitting v. Sulzer*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998); emphasis added in bold. In the present case, the two references relied upon by the Patent Office take divergent approaches to anterior cruciate ligament repair that teach away from one another. Moreover, there is no motivation or suggestion to take the groove from the implant of Beck and add it to the implant of Campbell. Campbell teaches away from making such changes. As support for their position, the Applicants submit two declarations of persons skilled in the art. The first declaration is the Declaration under 37 C.F.R. § 1.132 of Brad J. Larson, M.D. ("the Larson Declaration"). The second declaration is the Declaration under 37 C.F.R. § 1.132 of Raymond E. Olsen, M.S. ("the Olsen Declaration").

1. The Larson Declaration

In the Larson Declaration, Dr. Larson declares that he has been a practicing orthopedic surgeon for the last 18 years and that he conducted research on ACL reconstruction and has published in that area. [Larsen Declaration at ¶3.] Dr. Larson further declares that based upon education and experience, he considers himself to be a person of ordinary skill in the art of arthroscopy, and in knee and ligament reconstruction in humans. [Larson Declaration at ¶ 4.] Dr. Larson further declares that he has reviewed "the above-identified patent application, the rejected claims, the Official Action of 09/28/04 and the cited art" and that he understands their contents. [Larson Declaration at ¶ 5.] After reviewing the patent application, the rejected claims, the Official Action of 09/28/04 and the cited art, Dr. Larson disagrees with the Patent Office's conclusion that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the

bone blocks of the Campbell et al reference with **the longitudinal groove (see surface 17) of the Beck, Jr. et al. reference**, in order to insert an attachment screw and attach the attachment system to the patient's bone." [Larson Declaration at ¶5.]

As factual support for his conclusion, Dr. Larson first points out that as of the filing date of this application, there were two techniques for performing anterior cruciate ligament repair, the open technique and the endosteal technique:

> The original and oldest technique required an "**open**" knee wherein the bottom plate of the femur and the top plate of the tibia were disarticulated from one another to reveal their opposing inner surfaces. In this technique, the physician would drill a hole a predetermined distance into the opposing plates of the femur and the tibia. Thereafter, he would insert a bone plug shaped for each hole. Because of the extensive trauma to the knee imposed by this technique, a long recovery time was required. This is the technique and the associated implant disclosed in Campbell.
>
> A second and less invasive technique is the **endosteal** technique. This technique leaves the knee joint intact and uses an endoscope to drill a hole up through the tibia into the femur. See Exhibit B: U.S. Pat. 5,393,302 at FIG. 6 at element 34 ("femoral tunnel section") and Exhibit C: U.S. Pat. 6,306,168 at FIGs 10 and 11 at element 10 ("femoral tunnel"). A tendon or a bone-tendon-bone (BTB) graft having a diameter slightly less than the femoral bone tunnel is then slid up into the tunnel, positioned, tensioned and then fixed. This is the technique and the associated implant disclosed in Beck.
>
> [Larson Declaration at ¶6.]

In paragraph 7 of his declaration, Dr. Larson declares that he reviewed Campbell from the perspective of a person skilled in the art and that Campbell teaches that the purpose of his invention is to "retain the '**natural**' ligament to bone attachment in the donor tissue and to implant the bone piece at the recipients '**natural attachment site.**'" [Larson Declaration at ¶7.] As support for his statement, Dr Larson cites to the following text from Campbell, wherein Campbell states that the focus of his invention is replicating a "natural" attachment site and structures:

> This invention solves the problems outlined above with a xenograft, glutaraldehyde-preserved, replacement ligament that is harvested to retain a piece of donor bone in order to keep the **donor's natural**

> **attachment site intact**. Implantation of the bone piece **at the recipient's natural attachment site** results in a bioprosthetic ligament that has a **natural ligament-to-bone attachment** located **at the natural attachment site**, and this overcomes many problems of existing ligament prostheses.
>
> Generally, a method of attaching a replacement ligament according to a major aspect of the invention includes providing a ligament of suitable size and strength that has been harvested from a donor animal. The ligament has first and second end portions, and it is harvested so that at least a first bone piece remains attached to the first end portion in order to preserve intact a substantial portion of a **first natural ligament-to-bone attachment structure** of the donor animal at the first end portion.
>
> The first bone piece is **attached to a first bone of the patient at the natural attachment site** on the first bone and the second end portion of the ligament is attached to a second bone of the patient.
>
> The ligament may be harvested with a bone piece at each end. In addition, it may be tanned and processed with a glutaraldehyde solution, the bone pieces may be implanted in recesses formed in the bones of the patient at the natural attachment sites, and the bone pieces may be pinned in place. **In these ways, the surgeon can more closely replicate the natural attachment structures being replaced**.
>
> [Campbell at col. 1, line 61 to col. 2, line 24; emphasis added in bold.]

Thus, Dr. Larson pointed out that one skilled in the art interprets Campbell as teaching one skilled in the art how to "replicate the natural attachment structures" at the "natural attachment site."

In paragraph 8 of his Declaration, Dr Larson points out how Campbell "expressly teaches away from using implants that require arthroscopy and endosteal bone tunnels." [Larson Declaration at ¶8.] Specifically, Dr. Larson points to the portion of Campbell where Campbell begins by teaching that "**success depends upon proper attachment to host bone**":

> Replacement ligaments can restore performance where native structures rupture beyond repair. But **success depends on proper attachment to the host bone**. Thus, the **manner** in which this is

> done and the related **details of prosthesis construction** are **important**.
>
> [Campbell at col. 1, lines 13-17; emphasis added in bold.]

Dr. Larson then points out that "[i]n another sentence of the same paragraph, Campbell teaches that the '**manner**' of implantation, as well as the '**details of prosthesis construction** are **important**.'" [Larson Declaration at ¶8.] According to Dr. Larson, "By saying that the 'manner' of implantation and the '**details of prosthesis construction** are **important**,' Campbell was closing his prosthesis to changes in construction that would alter the inventive aspects features invention." [Larson Declaration at ¶8.]

According to Dr. Larson, one of the "**manners**" of implantation that Campbell specifically **taught away** from was the use of "**endosteal tunnels drilled in the bone**." [Larson Declaration at ¶8.] As support, Dr Larson cites to the following text from Campbell which **teaches away** from the use of "**endosteal tunnels drilled in the bone**" and points out several problems with that manner of implantation, including "ligament stretch, impaired performance, spicules that abrade ligaments, and synovial fluid in the intraosseous space.":

> Consider, for example, an injured knee joint having a damaged anterior cruciate ligament. Attachment of a replacement ligament according to **existing techniques** may involve **forming tunnels** in the **femur and tibia (the host bones)**. The tunnels are formed so that each extends through one of the host bones from an entrance or proximal end of the tunnel at the natural ligament attachment site to an exit or distal end of the tunnel at an outer surface of the host bone.
>
> Each end of the replacement ligament is passed through one of the tunnels, from the proximal end to the distal end where it is anchored to the outer surface of the host bone by such means as stapling. This results in the replacement ligament spanning the intra-articular region between the natural attachment sites somewhat like a natural ligament, but it also results in certain problems that need to be overcome.
>
> For example, the **replacement ligament extends beyond the natural attachment sites** and **all the way through the tunnels** to the outer surfaces on the other side of each host bone. This **results in the replacement ligament being able to stretch over a greater**

> **length than a natural ligament** (from the outer surface of the femur to the outer surface of the tibia), and this **impairs performance**.
>
> In addition, **formations** such as **bone spicules** can form at the entrance to each of the tunnels. These tend to **abrade the replacement ligament**, cause **fatigue** of the material, and break off particles which can cause **irritation**.
>
> Furthermore, the **tunnels** provide access to the host bone interior. As a result, **synovial fluid can migrate from the intra-articular region between host bones into the bone tunnels**. Thus, any activity in the intra-articular region, such as **infection**, can be easily **communicated** into the bone interior and result in **intra-osseous complications**. Similarly, activity within the bone can be easily communicated to the intra-articular region.
>
> Consequently, it is desirable to have a **new** and improved **replacement ligament** and **attachment method** that overcomes these concerns.
>
> [Larson Declaration at ¶ 8, citing Campbell at col. 1, lines 18-58; emphasis added in bold.]

Dr. Larson then points out that in the last sentence of the above quote, Campbell teaches that **both** his "**replacement ligament**" (*i.e.*, BTB) and the "**attachment method**" are required to overcome these concerns. [Larson Declaration at ¶8, page 6.] Dr. Larson then concludes that "Campbell teaches away from the use of endosteal tunnels and endosteal fixation." [Larson Declaration at ¶8, page 6.]

Upon reviewing Campbell, Dr. Larson also renders his "opinion and conclusion that Campbell's replacement ligament (BTB) is so large that it could never be implanted endosteally. The recipient site would have to be prepared through an **open** arthrotomy incision and the donor graft would be so large that it would have to be placed through a large incision as well." [Larson Declaration at ¶9.]

In paragraph 10 of his declaration, Dr. Larson renders his opinion "opinion that adding grooves to each of the 'bone plugs' of Campbell's replacement ligament (BTB) so that each 'bone plug' could be fixed with an interference screw would defeat the expressly stated object of Campbell's invention." [Larson Declaration at ¶9.] According to Dr. Larson, "Campbell wants to maintain the natural attachment site of the ligament so

he fixates the graft transversely by placing a 'stainless steel pin' through each of the bone plugs and the patient's bone into which they are anchored." [Larson Declaration at ¶10, citing to Campbell at FIG. 4 and at col. 4, lines 26-40 discussing FIG. 4.] "If one skilled in the art adheres to Campbell's 'manner of attachment,' which Campbell says is 'important' [Campbell at col. 1, lines 16-17], that skilled person would never think of using any type of interference fixation." [Larson Declaration at ¶10.] According to Dr. Larson, "An interference fixation, by definition, would interfere between the graft and the host tissue" and "Specifically, placing a interference screw between the donor bone (even if grooved) and the recipient bone would displace the donor bone away from the recipient bone at that point and defeat the natural attachment which Campbell teaches as 'important.'" [Larson Declaration at ¶10.] Finally, Dr. Larson points out that "when the interference screw pushes the donor bone away from the recipient bone at the screw site, it would allow synovial fluid to enter the intraosseous space, thereby defeating Campbell's solution to this problem." [Larson Declaration at ¶10.]

According to Dr. Larson, if "one skilled in the art wanted to implant the BTB of Campbell that was modified to include grooves for interference screws, it would require a combination of techniques that was neither taught or suggested in Campbell or Beck." [Larson Declaration at ¶11.] "Rather, the combination was negated by the teachings in both Campbell and Beck." [Larson Declaration at ¶11.] "An interference screw could theoretically be positioned through an endosteal tunnel and then screwed in between the groove on the donor bone plug and the recipient bone to fix the donor bone plugs (albeit poorly)." [Larson Declaration at ¶11.] "However, this method is expressly taught away from by Campbell because the synovial fluid would flow unabated into the open endosteal tunnels." [Larson Declaration at ¶11.] "So, therefore if I were to adhere to the essence of the concepts presented in Campbell, and Campbell's important "manner" of implantation, I would perform an open arthrotomy incision (a large incision), not use endosteal tunnels, and fixate the graft transversely, as did Campbell." [Larson Declaration at ¶12.]

Separately Dr. Larson declared, as a physician skilled in the art, that "[t]here is no way I could perform the entire procedure of Campbell arthroscopically and I would not want to use interference fixation - even given the advances and choices of

fixation offered today - regardless of whether or not each of the bone plugs of the graft had a groove on it." [Larson Declaration at ¶13.]

In paragraph 14 of his declaration, Dr. Larson addresses the teachings of Beck in combination with Campbell, and points out that the teachings in Beck of using an "endosteal tunnels" and "ligaments against bone in bone tunnels" is the "manner" of implantation and the type of ligament construct (BTB) that is expressly taught away from by Campbell:

> The second reference, Beck, is entitled "Endosteal Anchoring Device For Urging A Ligament Against A Bone." On its face, the "manner" of implantation disclosed in Beck is "endosteal" and uses "bone tunnels." [See also Beck at col. 6 line 33 ("a bone tunnel is generally formed in the femur and/or tibia for positioning the natural or synthetic ligament graft therein.")] Thus, the manner of implantation taught in Beck is manner that is expressly taught away by Campbell. Secondly, as Beck's title reflects, Beck's invention is directed to "urging a ligament against a [recipient] bone." However, Beck's invention was directed to making a natural bone-to-bone (donor bone to recipient bone) connection. [See Campbell at FIG. 4.] In fact, Campbell taught away from having the donor tendon contact the recipient bone in the bone tunnel, stating: "In addition, **formations** such as **bone spicules** can form at the entrance to each of the tunnels. These tend to **abrade the replacement ligament**, cause **fatigue** of the material, and break off particles which can cause **irritation**." [Campbell at col. 1, lines 43-47; emphasis added in bold.] Thus, on their face, the "manner" and strategy for implantation disclosed in Campbell and Beck are opposites.
>
> [Larson Declaration at ¶ 14; emphasis in original.]

Thus, after reviewing both Campbell and Beck, Dr. Larson concludes that "on their face, the 'manner' and strategy for implantation disclosed in Campbell and Beck are opposites."

Separately, Dr. Larson also addresses the endosteal anchoring device of Beck. In particular, Dr. Larson points out that the anchoring device of Beck is complicated, has spikes, and are formed three dimensionally, and would be impossible to make out of bone, particularly since Beck never taught how to make them out of bone:

> Beck teaches a soft tissue graft fixated endosteally with an "endosteal anchoring device is manufactured from a material

> suitable for sterilization and human implantation and comprised of either a permanent non-biodegradable material or a biodegradable material capable of being absorbed by the body while maintaining the essential rigid qualities required to accommodate its anchoring functions." [Beck at col. 6, lines 42-48.] The endosteal anchoring devices of Beck are complicated; they have spikes on them (FIGS. 4, 7 and 10), are formed 3-dimensionally, and expand (FIG. 10). Beck does not disclose how to make his devices, particularly out of bone. Given the thought processes in 1999 and the current technology today, it would be difficult, if not impossible, to manufacture Beck's devices out of bone. So, Beck is using endosteal fixation, but not directly placing a screw or threaded device against the graft to avoid "damage to the cross-fibers of the ligament or tissue." Beck's groove is on his foreign fixation device and not his graft – another major difference.
>
> [Larson Declaration at ¶ 17.]

Based upon what Beck discloses that could have been made, Beck's groove is on a foreign fixation device, and not the actual graft itself.

Dr. Larson concludes his declaration by addressing the ultimate conclusion of obviousness reached by the Patent Office. [Larson Declaration at ¶16.] "From the view of one skilled in the art, Campbell and Beck are disclosing implantable devices for use in very different manners of implantation, where such manners of implantation are [as stated by Campbell] "important," to solve very different problems." [Larson Declaration at ¶16.] "It is my opinion and conclusion, as a person skilled in the art, that it would not have been obvious to take the groove feature of Beck's endosteal anchor and add it to the bone plugs of Campbell to create an invention that neither teaches how to use, nor how to solve the new problems created." [Larson Declaration at ¶16.] Accordingly, Dr. Larson, as a person skilled in the relevant art, would not have found the Applicants' xenograft BTB to have been obvious over Campbell in view of Beck.

2. The Olsen Declaration

In the Olsen Declaration, Mr. Olsen declares that based upon his education listed in paragraphs 2 and 3 of his declaration, and the experiences listed in paragraphs 4-6 of his declaration and in his curriculum vitae (Exhibit A), he considers himself to be "a person of ordinary skill in the art of BTB structure, testing and modes of

implantation.." [Olsen Declaration at ¶7.] It is also significant that Mr. Olsen declares that he is a co-inventor on the four listed U.S. patents related to endosteal ligament mounting and ACL repairs. [Olsen Declaration at ¶6.] Dr. Larson further declares that he has reviewed "the above-identified patent application, the rejected claims, the Official Action of 09/28/04 and the cited art" and that he understands their contents. [Larson Declaration at ¶ 5.]

After reviewing the patent application, the rejected claims, the Official Action of 09/28/04 and the cited art, Mr. Olsen disagrees with the Patent Office's conclusion that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bone blocks of the Campbell et al reference with **the longitudinal groove (see surface 17) of the Beck, Jr. et al. reference**, in order to insert an attachment screw and attach the attachment system to the patient's bone." [Olsen Declaration at ¶8.]

As factual support for his conclusion, Mr. Olsen points out that at the filing date of the present application, there were two techniques for performing anterior cruciate ligament repair- the open technique and the endosteal technique. [Olsen Declaration at ¶9.] These are the same techniques referenced in ¶6 of the Larson Declaration. Mr. Olsen, like Dr. Larsen, declares that Campbell teaches the surgical technique wherein the knee is "opened such that the femur and the opposing tibia are partially disarticulated" and then the bone blocks are inserted into their respective holes. [Olsen Declaration at ¶10.] Mr. Olsen, like Dr. Larsen, declares that Beck discloses the endosteal technique wherein bone tunnels are drilled "through the tibia and into the femur" as shown in his U.S. Pat. 6,306,168 at FIGs. 10 and 11 at element 10 ("femoral tunnel), and where the ends (anchor bodies) of the BTB are fixed in place in the endosteal tunnels by an interference screw. [Olsen Declaration at ¶11.] Mr. Olsen declares that "one skilled in the art would have no reason or motivation to put a groove on the bone block of Campbell." [Olsen Declaration at ¶12.] In particular, Mr. Olsen declares that if one skilled in the art added the grooves of Beck to the BTB of Campbell and employed Campbell's open technique, one skilled in the art would not would not be able to insert the second interference screw in the joint which must be closed to seat the second bone block in its respective hole:

> I will assume for the sake of argument that one added the grooves of Beck to the BTB of Campbell. **A first screw could be inserted to fix one bone block of the BTB of Campbell to the**

> **corresponding hole in the femur because the joint is open and accessible to a screw and a driver for inserting the screw.** However, **when the second bone block is fixed in the corresponding hole in the tibia, it is desirable for the sake of proper tensioning and isometry that the joint be in a shallow degree of flexion thus closing access to the second bone block. Neither Beck nor Campbell teaches how to insert the second screw in a closed joint.** This is why Campbell used **stainless steel pin** 32 in hole 26 that traversed the tibia and the bone block. See Campbell at FIG. 4 and at col. 4, lines 38-40 ("There, it is attached to the tibia28 by suitable means such as a second stainless steel pin 32 through hole 26."). Thus, the combination of Campbell over Beck would not motivate one skilled in the art to put a groove in each of the bone blocks of Campbell's BTB because the combination of Campbell and Beck (even if combinable) does not disclose how to use or install such a graft. Clearly, one skilled in the art would have no motivation to make a BTB that could not be installed, or that would require techniques neither taught nor suggested in Campbell or Beck. However, more importantly, Campbell and Beck are disclosing BTBs for use in very different techniques. Hence, it is my opinion and conclusion, as a person skilled in the art, that it would not have been obvious to take the groove feature of Beck and add them to the bone blocks of Campbell to create an invention that neither teaches how to use.
>
> [Olsen Declaration at ¶13; emphasis added in bold.]

Thus, it is Mr. Olsen's declared statement, as a person skilled in the art, that one skilled in the art would not have been motivated to place the groove of Beck on the bone blocks of Campbell's BTB because the resulting BTB could not have been inserted using Campbell's open technique. Likewise, Dr. Larsen said that he could not have implanted a BTB of Campbell (with or without the groove) by the endosteal technique such as disclosed in Beck. [Larsen Declaration at ¶¶9, 12 and 13.]

Thus, both the Larson and Olsen declarations provide factual evidence, the opinions of two persons skilled in the art and their factual bases for their opinions, that Campbell and Beck **teach away** from their combination, particularly the addition of a groove to the bone block of Campbell, which would defeat Campbell's important "manner" of implantation and the problems that it solved. *See Monarch Knitting v. Sulzer*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998) ("A prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be

discouraged from following the path set out in the reference, or **would be led in a direction divergent from the path taken by the applicant.**"); emphasis added in bold. For all these reasons, the combination of Campbell in view of Beck would not have made a *prima facie* case of obviousness against the claimed invention. *See In re Fine*, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988) ("error to find obviousness where references 'diverge from and teach away from the invention at hand'"); *citing Gore v. Garlock*, 220 USPQ 303, 311 (Fed. Cir. 1983).

In addition, both the Larson and Olsen declarations provide factual evidence, the opinions of two persons skilled in the art and their factual bases for their opinions, that there would be no motivation to place the groove of beck on the BTB of Campbell because there is no teaching in either of the references on how such a modified BTB could be implanted.

For all these reasons, the combination of U.S. Pat 5,067,962 ("Campbell") in view U.S. Patent No. 5,961,520 ("Beck") would not make a *prima facie* case of obviousness against claims 1, 2, 4, 8, 9, and 31-40 3, 7-11 under 35 U.S.C. §103(a). The allowance of claims 1-2, 4, 8-9 and 31-40 is respectfully requested.

B. The Addition of the groove of Beck to the graft of Campbell fails to provide a graft that would be useful in orthopedic surgery

The addition of **the longitudinal groove of the Beck, Jr. et al reference** to the shaped xenograft bone-ligament-bone (aka Bone-Tendon-Bone) graft of Campbell would not provide a xenograft bone-tendon- bone graft that would be **useful in orthopedic surgery**. Claim 1 of the Applicants invention is directed to "A xenogenic bone-tendon-bone graft **useful in orthopedic surgery**. . ." Specifically, the bone block ends of the bone-ligament-bone graft of Fig. 3 of Campbell (which is relied upon by the Patent Office) are not dowels as alleged. They are frustoconical in shape wherein the ends of each bone block that are furthest from the ligament have a smaller diameter (and circumference) than the ends of the bone block that are attached to the ligament. By way of analogy, the bone blocks of the xenogeneic bone-ligament-bone graft of Campbell are shaped like tapered bottle corks that fit into the appropriately tapered hole. This is shown in Fig. 4 of Campbell. In order to retain the tapered bone blocks in their correspondingly shaped

tapered holes, Campbell discloses the use of holes 25 and 26 in the tapered blocks of Figure 3, which receive a stainless steel pins 30 and 32 to anchor the corresponding bone blocks to the femur and the tibia:

> Installation of the replacement ligament 11 as an anterior cruciate ligament between a femur 27 and a tibia 28 results in the replacement ligament installation 10 illustrated in **FIG. 4**. The bone plug 23 is implanted or placed within a first recess 29 formed by suitable known means in the femur 27 at the naturally occurring attachment site on the femur 27 of the ligament being replaced. There, it is attached or anchored to the femur 27 by suitable means such as a **first stainless steel pin 30 through the hole 25**. Similarly, the bone plug 24 is placed within a second recess 31 formed in the tibia 28 at the naturally occurring attachment site on the tibia 28. There, it is attached or anchored to the tibia 28 by suitable means such as a **second stainless steel pin 32 through the hole 26**.
>
> [Campbell at col. 4, lines 26-40; emphasis added in bold.]

Thus, Campbell used horizontal pins, which ran perpendicular to the direction of pull on the bone blocks, to prevent the tapered (cork-shaped) bone blocks from falling out, or being pulled out of their tapered holes.

There is no express suggestion in either Campbell or Beck to take **the longitudinal groove of the Beck, Jr. et al reference** and add it to the side of the tapered xenograft bone-ligament-bone (aka Bone-Tendon-Bone) graft of Campbell. The reason that there is no express suggestion to do so is because any interference screw that pressed against the cork shaped graft of Campbell would have a downward component of force on the opposing wall that would literally pop the cork shaped graft out of the tapered hole. Specifically, Applicants have copied Fig. 2 of Campbell but deleted all of the lines pointing to the number of the various elements. For purposes of this analysis, Fig 2 is analogous to Fig. 4 of Campbell, because the shape of the tapered bone block is the same and there are less interfering lines. In the copied (but enlarged) Fig. 2 shown as **page 18 herein**, the Applicants have added the opposing force vectors (bolded arrows **R** and **X**) to show the directly opposing forces that an interference screw would exert against the bone graft and the wall of the tapered hole in which it was inserted. Any interference screw that was wedged between hole wall **A** and tapered wall **B** of the bone graft would exert equal

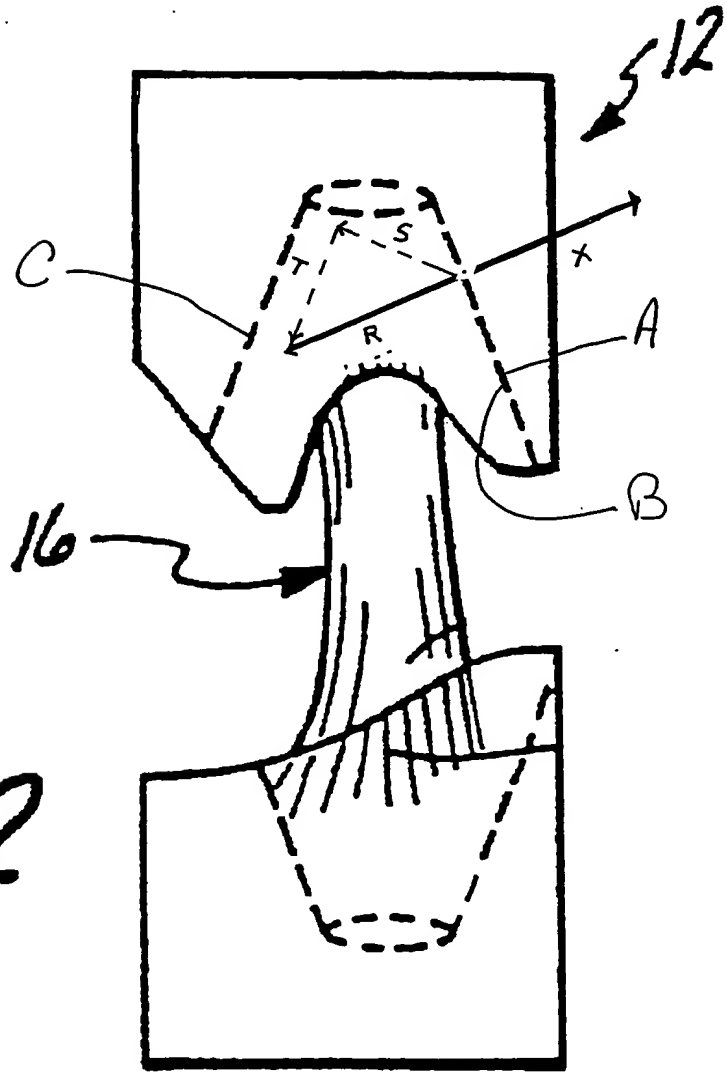
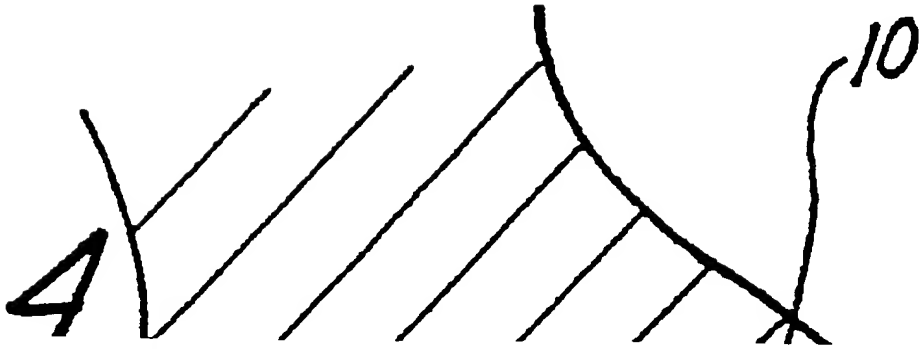


FIG. 2



but opposing forces perpendicular to each of wall **A** and wall **B**. The force **R** against wall B then gets transferred by the bone graft against opposing wall **C**. However, using conventional vector analysis, the force of vector **R** exerted by the tapered bone graft against transferred to opposing hole wall **C** may be resolved into two components shown as **S** and **T**. The line of action of the first component **S** is perpendicular to hole wall C. However, the line of action of the second component **T** presses the tapered bone plug downward along (parallel to) hole wall **C** and out of the hole. Referring to enlarged Fig. 2, the force **R** that is exerted by an interference screw positioned between walls **A** and **B** has a **desired component** of force **S** **perpendicular** to hole wall **C** that is **equal** to the **undesired component** of force **T** that is pushing the tapered (cork shaped) implant down and out of the hole. In short, the forces exerted by an interference screw on a groove in the sidewall of the cork shaped implant of Campbell would literally pop the cork (or cork shaped implant) out of its hole and not provide a graft within the scope of the Applicants' claims, *i.e.*, "a xenograft bone-tendon- bone graft that would be **useful in orthopedic surgery . . . .**" This is one reason why Campbell chose the lateral hole and stainless steel pin combination whereby the tapered graft was retained in its position by lateral pins that resisted all downward pressure, including downward (pulling) pressure during use, until such time as bone remodeling occurred. Any attempt to retain the tapered implant of Campbell with an interference screw would be non-operative for its purpose and would lack utility. For these reasons, the combination of Campbell in view of Beck would not give rise to an operative embodiment of the Applicants' claimed invention.

Separately, the Applicants also wish to point out that the approaches taken by Campbell and Beck, to solving the problem of anterior cruciate ligament repair, are very different. Campbell's approach is to use as natural a B-T-B graft as possible positioned in as natural a position as possible. This means a unitary B-T-B graft having the natural bone to tendon connection at both ends of the tendon. In Campbell's approach, the tapered bone blocks at the ends of the tendons are machined to be received by correspondingly tapered holes in the patient's femur and tibia. Thus, in Campbell's approach, only the bone component of the B-T-B graft ever contacts patient bone. The tendon never touches patient bone.

In contrast, Beck's approach is multi-component with a lot of assembly required. In particular, Beck takes opposing ends of a length of tendon and runs the opposing ends up and down grooves in each of the unitary or assembled anchor bodies. The amount of tendon surface that contacts patient bone is almost as great as the amount of bone anchor surface that contacts patient bone. This means that the assembled B-T-B of Beck relies upon an unnatural connection wherein tendon contacts the inside of the patient bone in a bone tunnel. Moreover, in Beck's approach, the interference screw compresses both soft tendon and the bone anchor against the walls of a bone tunnel so as to retain both in the tunnel.

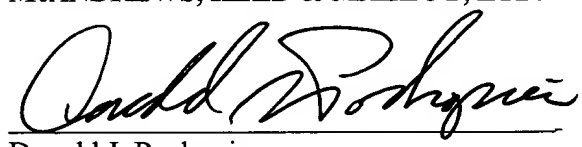
CONCLUSION

Claims 1-2, 4, 8-9 and 31-40 stand rejected. In view of the arguments and evidence provided herein, all bases for rejecting claims 1-2, 4, 8-9 and 31-40 under 35 U.S.C. §103(a) for alleged obviousness have been rebutted. The allowance of claims 1-2, 4, 8-9 and 31-40 is respectfully requested.

If the Examiner feels that a telephone call would advance the prosecution of this application, he is invited to telephone the undersigned attorney at the telephone number provided below.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By: 

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